Initial Approval Date: April 21, 2021

CRITERIA FOR PRIOR AUTHORIZATION

Hypercholesterolemia Agents

BILLING CODE TYPE For drug coverage and provider type information, see the KMAP Reference Codes webpage.

MANUAL GUIDELINES Prior authorization will be required for all current and future dose forms available. All medication-specific criteria, including drug-specific indication, age, and dose for each agent is defined in Table 1 below.

Alirocumab (Praluent®)
Bempedoic Acid (Nexletol™)
Bempedoic Acid/Ezetimibe (Nexlizet™)
Evinacumab-dgnb (Evkeeza™)
Evolocumab (Repatha®)
Lomitapide (Juxtapid®)

GENERAL CRITERIA FOR INITIAL PRIOR AUTHORIZATION: (must meet all of the following)

- Must be approved for the indication, age, and not exceed dosing limits listed in Table 1.
- For all agents listed, the preferred PDL drug, if applicable, which treats the PA indication, is required unless the patient meets the non-preferred PDL PA criteria.
- Must be prescribed by or in consultation with a cardiologist or endocrinologist.[1]
- For treatment of established atherosclerotic cardiovascular disease (ASCVD):[1-3]
    - Patient must meet one of the following:
        - Coronary heart disease (acute coronary syndrome, history of myocardial infarction, stable or unstable angina, coronary revascularization).
        - Cerebrovascular disease (history of stroke or transient ischemic attack).
        - Peripheral arterial disease.
- For treatment of primary hyperlipidemia including heterozygous hypercholesterolemia (HeFH):[1-4,6]
    - Patient must meet one of the following:
        - Dutch Lipid Network score > 5.
        - Simon-Broome criteria indicates definite or possible familial hypercholesterolemia (FH).
        - Genetic testing results confirming the presence of a pathogenic variant at one allele of the LDLR, APOB and/or PCSK9 gene.
- For treatment of homozygous familial hypercholesterolemia (HoFH):[4-6]
    - Patient must meet one of the following:
        - Genetic testing results confirming the presence of biallelic pathogenic variants in LDLR, APOB and/or PCSK9 genes.
        - Untreated LDL-C ≥ 560 mg/dL.
        - Untreated LDL-C ≥ 400 mg/dL and at least one parent with FH.
        - Untreated LDL-C ≥ 400 mg/dL and evidence of aortic valve disease or xanthomata in patients < 20 years of age.
- Patient must have had an adequate trial for at least 90 consecutive days of maximally tolerated doses of statin therapy (Table 2) in combination with ezetimibe and an inadequate response (LDL-C ≥ 70 mg/dL) to at least two high intensity statins or contraindication to all drugs listed in Table 2.[1]
- Prescriber must provide the patient's baseline LDL-C.

LENGTH OF APPROVAL (INITIAL): 6 months

CRITERIA FOR RENEWAL PRIOR AUTHORIZATION: (must meet all of the following)

- Must not exceed dosing limits listed in Table 1.
- Patient must have an LDL-C < 70 mg/dL or a reduction by at least 50% from baseline.[1]

LENGTH OF APPROVAL (RENEWAL): 12 months

FOR DRUGS THAT HAVE A CURRENT PA REQUIREMENT, BUT NOT FOR THE NEWLY APPROVED INDICATIONS, FOR OTHER FDA-APPROVED INDICATIONS, AND FOR CHANGES TO AGE REQUIREMENTS NOT LISTED WITHIN THE PA CRITERIA:

- **THE PA REQUEST WILL BE REVIEWED BASED UPON THE FOLLOWING PACKAGE INSERT INFORMATION: INDICATION, AGE, DOSE, AND ANY PRE-REQUISITE TREATMENT REQUIREMENTS FOR THAT INDICATION.**

LENGTH OF APPROVAL (INITIAL AND RENEWAL): 12 months

Table 1. FDA-approved age and dosing limits for Cholesterol Agents[8-13]

Agents	Indication(s)	Age	Dosing Limits
PCSK9 Inhibitors			
Alirocumab (Praluent®)	Reduce the risk of myocardial infarction (MI), stroke and unstable angina requiring hospitalization in adults with established CVD Primary hyperlipidemia (includes HeFH) HoFH	≥ 18 years	150 mg SQ every 2 weeks (may be given as 300 mg SQ every 4 weeks)
Evolocumab (Repatha®)	Reduce the risk of MI, stroke and coronary revascularization in adults with established CVD Primary hyperlipidemia (includes HeFH) HoFH	Established CVD or primary hyperlipidemia: ≥ 18 years HoFH: ≥ 13 years	Established CVD or primary hyperlipidemia: 140 mg SQ every 2 weeks HoFH: 420 mg SQ once monthly
Microsomal Triglyceride Transfer Protein Inhibitor			
Lomitapide (Juxtapid®)	Reduce LDL-C, TC, apo B and non-HDL-C in HoFH	≥ 18 years	60 mg orally daily
Adenosine Triphosphate-Citrate Lyase (ACL) Inhibitors			
Bempedoic acid (Nexletol™)	HeFH Reduce LDL-C in patients with established ASCVD	≥ 18 years	180 mg orally daily
Bempedoic acid and ezetimibe (Nexlizet™)	HeFH Reduce LDL-C in patients with established ASCVD	≥ 18 years	180 / 10 mg orally daily
Angiopoietin-like 3 (ANGPTL3) Inhibitor			
Evinacumab-dgnb (Evkeeza™)	HoFH	≥ 12 years	15 mg/kg IV infusion every 4 weeks

Table 2. Statin Therapy[6]

High-Intensity Statin Therapy	Moderate-Intensity Statin Therapy	Low-Intensity Statin Therapy
Atorvastatin 40-80 mg Rosuvastatin 20-40 mg	Atorvastatin 10-20 mg Rosuvastatin 5-10 mg Simvastatin 20-40 mg Pravastatin 40-80 mg Lovastatin 40 mg Fluvastatin 80 mg Pitavastatin 1-4 mg	Simvastatin 10 mg Pravastatin 10-20 mg Lovastatin 20 mg Fluvastatin 20-40 mg

Notes:

Kynamro® (mipomersen sodium)	As of August 2, 2019, NDA 203568 for Kynamro was withdrawn and the product has been discontinued.[7]

References

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3. Mach F, Baigent C, Catapano AL, et al. 2019 ESC/EAS Guidelines for the management of dyslipideaemias: lipid modification to reduce cardiovascular risk: The Task Force for the management of dyslipidaemias of the European Society of Cardiology (ESC) and European Atherosclerosis Society (EAS). European Heart Journal 2020;41(1):111-188. Available at: https://academic.oup.com/eurheartj/article/41/1/111/5556353. Accessed 03/17/2021.
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9. Nexlizet (bempedoic acid/ezetimibe) [prescribing information]. Ann Arbor, MI: Esperion Therapeutics, Inc.; February 2020.
10. Praluent (alirocumab) [prescribing information]. Tarrytown, NY: Regeneron; April 2021.
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